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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,458	11/16/2001	Bruce Russell Stevens	UF-283	3818

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EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/22/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,458	STEVENS ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12-21,38-40 and 42-60* is/are pending in the application.

4a) Of the above claim(s) *46-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 12-21, 38-40, 42-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-7, 12-21, 38-40, and 42-45 in Paper No. 13, submitted 19 June 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In the same paper, Applicants added new claims 46-60, which correspond to cancelled claims 8-11 and 27-37. The newly added claims are not considered to be part of the invention of Group I. Claims 46-49 comprise genetically transforming a host, which is not required by the invention of Group I. Claim 50 and 55-58 are drawn to compositions that can comprise any compound that disrupts any organic solute transporter/ligand-gated ion channel protein in any pest. The invention of Group I, however, does not require compounds that are not amino acids. The compositions of claims 51-54 comprise amino acids. However, such compositions can be used for other purposes, such as in tissue culture media. The method for identifying a CAATCH1 protein or detecting a CAATCH1 gene of claims 59 and 60 the method for pest control of Group I. New claims 46-60 are withdrawn from consideration as being drawn to non-elected inventions.

Information Disclosure Statement

2. The entry for Stevens, Bruce, R., "Amino Acid Transport in Intestine," (Cite No. R8), was lined through because the copy of this reference was defective. Text was missing in many of the pages of the provided copy.

Specification

3. The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable codes, for example at page 5, lines 11, 16, and 20, page 28, line 28, and page 31, line 23. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable codes. See MPEP § 608.01.

4. Figure 1 contains open circles and filled-in circles. However, it is not clear what these symbols represent. The brief description of Figure 1 does not provide a legend. Correction/clarification is required. New matter must be avoided.

5. The sentence on page 17, lines 15-16 indicates that Figure 1 shows a CAATCH1 polynucleotide sequence. However, Figure 1 does not show any type of sequence. Correction/clarification is required. New matter must be avoided.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-7, 19-21, 38, and 40 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 19-21, 38, and 40 of copending Application No. 10/298,974. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Instant claims 1-7, 19-21, 38, and 40 are identical in scope with claims 1-7, 19-21, 38, and 40 of the co-pending application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 12-21 and 39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-21, 39, and 40 of copending Application No. 10/298,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both co-pending applications encompass common subject matter. The scope of the claims of the instant application fall entirely within the scope of the co-pending application. It is noted that the co-pending application is a continuation-in-part of the instant application. However, a terminal disclaimer is

still required to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-7, 12-21, 38-40, and 42-45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 38, and 40: the claims are indefinite because the preambles of the claims are inconsistent with the last step of the claimed methods. The first line of the claims indicates that the methods are for pest control. However, the last step of the claims only indicates that a protein is disrupted, or that an amino acid is administered, or that solute transport or ion channel activity is disrupted. It is suggested that the last line of claim 1 be amended to indicate that the compound leads to pest death; that the last line of claim 38 be amended by inserting, --to cause death of the pest--; and that the last line of claim 40 be amended to indicate that the inhibition leads to death of the pest.

Further in claims 1, 38, and 40: the recitation, "pest control" in line 1 of claim 1, and "controlling a pest" in line 1 of claims 38 and 40 also render the claim indefinite. It is not clear what is meant by "control" or "controlling" a pest. It is not clear what types of control are

encompassed by the claims. Page 15, lines 24-27, indicates that "pest control" includes pesticidal as well as pest aversion activity. However, the open term, "includes," makes this definition unclear as to what else "pest control" can encompass. The metes and bounds of the claims are unclear. It is suggested that the preamble of the claims be amended to indicate that the methods are for causing pest death, as the specification, in Examples 9-14, teaches that feeding L-methionine or L-leucine to insect larvae led to their death.

In claim 42: the recitation, "another pesticide" renders the claim indefinite. Neither claim 42, nor parent claim 1, mentions that the compound is a pesticide.

In claim 43: the recitation, "pesticide is *Bacillus thuringiensis*" renders the claim indefinite. *Bacillus thuringiensis* is a bacterium, not a pesticide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn towards a method for pest control comprising exposing said pest to a compound which disrupts a CAATCH1 protein comprising the amino acid sequence of SEQ ID NO: 2, or any portion of said sequence, having CAATCH1 biological activity.

The specification indicates that a cDNA (SEQ ID NO: 1) encoding a cation-amino acid transporter/channel protein, CAATCH1 (SEQ ID NO: 2), was isolated from a midgut cDNA library from the hornworm, *Manduca sexta* (Example 1). Nucleotide sequences encoding CAATCH1 proteins were also isolated from mRNA of the mosquito, *Aedes aegypti*, and the Colorado potato beetle, *Leptinotarsa decemlineata*. The mosquito and potato beetle CAATCH1 nucleotide sequences were identical to SEQ ID NO: 1 (Examples 2 and 3).

However, the specification does not describe portions of SEQ ID NO: 2 that retain CAATCH1 biological activity, or pests that contain said portions. The specification does not describe regions of functional importance, or sequences of SEQ ID NO: 2 that may be changed without altering activity. The specification does not correlate any sequence besides SEQ ID NO: 2 with CAATCH1 activity. See Fiers 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing any portion of SEQ ID NO: 2 that retains CAATCH1 biological activity, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude sequences, or pests comprising said sequences, encompassed by the claims.

10. Claims 1-7 12-21, 38-40, and 42-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of for killing pests having alkaline gut compartments, by feeding L-methionine or L-leucine to the pests, does not reasonably

provide enablement for killing any other types of pests, or for controlling all pests in any other manner, or other compounds which, when fed to pests, disrupts organic solute/ligand gated-ion channel proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards a method for controlling any pest in any manner, comprising exposing said pest to a compound which disrupts any organic solute/ligand-gated ion channel protein; or wherein said compound disrupts CAATCH1 protein function; or wherein said CAATCH1 protein comprising SEQ ID NO: 2 or any portion thereof having CAATCH1 biological activity; or wherein said method comprises exposing said pest to any amino acid which disrupts said organic solute/ligand-gated ion channel protein; or wherein said pest has an alkaline gut compartment or a V-type ATPase in its gut or midgut region; or a method for controlling any pest in any manner comprising administering an effective amount of any amino acid or analog thereof; or wherein said method comprises inhibiting within said pest any solute transport or ion channel activity; or wherein said compound is applied with any other pesticide; or wherein said compound is applied in a formulation comprising a carrier.

The specification teaches that a cDNA (SEQ ID NO: 1) encoding a cation-amino acid transporter/channel protein, CAATCH1 (SEQ ID NO: 2), was isolated from a *Manduca sexta* midgut cDNA library (Example 1). Nucleotide sequences encoding CAATCH1 proteins were also isolated from mRNA of the mosquito, *Aedes aegypti*, and the Colorado potato beetle, *Leptinotarsa decemlineata*. The mosquito and potato beetle CAATCH1 nucleotide sequences were identical to SEQ ID NO: 1 (Examples 2 and 3).

The specification also teaches that *M. sexta* larvae fed a commercially obtained, hydrated reconstituted meal stock, or the same stock supplemented with L-methionine. All larvae that were fed the methionine died within 3 days of feeding, whereas all of the control larvae proceeded in their developmental course. The mortality of *M. sexta* larvae was also assayed by feeding with eggplant leaves sprayed with an aqueous solution of methionine. 100% of the larvae died at all test doses (Example 9). In another assay, leaves of eggplant were sprayed with a deionized water/Silwet-77 solution containing varying concentrations of methionine. According to Figure 3, all of the larvae that were fed with the treated leaves again died (Example 10). 100% mortality was also observed when *L. decemlineata* larvae were exposed to leaves of eggplant that were sprayed with water containing varying concentrations of methionine (Example 11). The specification also teaches increasing mortality rates of *A. aegypti* larvae that were placed in water containing increasing concentrations of L-methionine (Example 13). The specification also teaches that water containing L-proline had no effect on *A. aegypti* larvae (Example 14).

However, the specification does not teach any other compounds, besides L-methionine, that increased mortality when fed to pests. The specification does not teach that any other amino acids had any effect on any pest. Further, as discussed above, the specification teaches that L-proline did not have on *A. aegypti* larvae. The specification does not teach any other compound that may be used to control pests upon exposure to it. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine what other compounds may be used to control pests. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001,

1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, while the specification discusses the properties of CAATCH1 (Example 3), it does not teach that L-methionine, or any other compound, disrupted CAATCH1 or any organic solute transporter/ligand-gated ion channel protein of any pest. Examples 9-11, 13, and 14 provides the results on mortality of insect larvae that were fed or placed in solutions comprising L-methionine. The examples do not make any correlation at all with these experiments and any organic solute transporter/ligand-gated ion channel protein of the tested pests. Nor does the specification teach how one would test the dead larvae to determine if any of these proteins were disrupted. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine if any solute transporter/ligand-gated ion channel protein was disrupted in any pest that was treated with L-methionine or any other compound.

Furtherstill, the specification does not enable the claimed methods for use with all types of pests. The specification only shows the effect of L-methionine on insects, and Example 15 provides a table showing that the insects tested have alkaline gut compartments in common. It is suggested that claims 1, 38, and 40 be amended to indicate that the pests are insects with alkaline gut compartments.

Furthermore, the specification does not enable one skilled in the art to control pests other than by causing larval death. The specification, on page 15, lines 24-27, indicates that "pest control" includes pest aversion activity that causes pests to avoid deleterious behavior such as mosquito biting, or a caterpillar eating an agricultural crop. However, Examples 9-11, 13, and 14 only show that the tested larvae died. As the method taught in the specification causes larval

death, it is not clear, or explained by the specification, how the claimed method can allow the treated pests to live and instead affect other types of "pest aversion activity." See Genentech, Inc. V. Novo Nordisk, A/S, *supra*. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

11. Claims 1-7, 12-21, 38-40, and 42-45 are rejected. Claims 46-60 are withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

September 16, 2003

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638